II. The Section 112, 2nd ¶ Claim Rejections

Claims 1-6 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim subject matter which Applicants regard as the invention. The rejection of various combinations of claims 1-6 are overcome or traversed as set forth immediately below.

1. The Examiner rejected claims 1 and 6 because the word "comprise" is interpreted as open claim language and allows for the presence of other components in the unstable solution making the claims unclear.

The Applicants have overcome this rejection by amending claims 1 and 6 to provide for the combination of two stable solutions which, when combined, form an unstable solution. However, the Applicants do not agree with the Examiner's position that the stable solution should not include components in addition to those that, when combined, form an unstable solution. As currently claimed, the invention is directed to a method whereby two stable solutions, each having an undefined number of ingredients, combine to form an unstable solution.

2. The Examiner rejected claim 1 under 35 U.S.C. under Section 112, second paragraph and under Section 101 because the claims do not set forth any steps involved in the method or process of step (d).

The Applicants have overcome this rejection by combining method steps (c) and (d) into a single method step.

3. The Examiner rejected claim 3 for claiming a Markush group improperly. In addition, the Examiner questioned the definiteness of claim 3 because the specification fails to disclose what is encompassed within the definition of certain biological materials listed in the Markush group.

The Applicants have overcome the Examiner's rejection of claim 3 by canceling claim 3 from the application and by replacing claim 3 with new claims 10-12. The new claims list the classes of biological materials that may be processed by the claimed methods using proper Markush language. Claims 11-12 recite subgroups of two of the types of biological materials listed in claim

10 using proper Markush group language.

4. The Examiner rejected claim 3 because several of the listed biological materials are allegedly open ended.

The Applicants traverse this rejection. A person skilled in the pertinent art would understand the scope of biological materials falling within each of the listed groups of biological materials. The Applicants do not have an obligation to provide an exhaustive list of biological materials that may be processed by the claimed methods. Instead, the Applicants need only provide a written description of the invention that is sufficient for one of skill in the art to practice the invention. The Applicants have complied with this requirement by providing a list of biological material groups that may be processed using the claimed methods.

5. The Examiner rejected claim 4 as being indefinite because the specification fails to teach the particular solutions which are encompassed by the claim. In addition, the Examiner objected to the recitation of certain staining solutions in the plural.

The Applicants traverse the Examiner's rejection of claim 4. It is the Applicant's position that one of skill in the art would understand the types of solutions that fall within each type of solution listed in claim 4. Furthermore, the use of plural language to describe some of the solutions is not indefinite. The plural language, such as "silver staining solutions" clearly refers to staining solutions that include a silver staining component. Since there are numerous recipes for silver staining solutions, the use of plural language to describe such solutions is proper.

For the reasons indicated above, the Applicants have either overcome or traversed the Examiner's claim objections under 35 USC, Section 112, second paragraph or 35 USC, Section 101.

III. Traverse Of The Obviousness Rejections

A. The McCormick et al. and Copeland et al. Rejection

Claims 1-3 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. (U.S. Patent 3,431,886) in view of Copeland et al. (U.S. Patent 5,650,327). It is

the Examiner's position that McCormick et al. teaches all aspects of claims 1-3 and 5 except for the mixing of reagents on a slide. The Examiner looks to the Copeland et al. reference for teaching the steps of applying a reagent staining solution to a slide and mixing the solution on the surface of the slide by applying a gas stream or two gas streams so as to form a vortex. The Examiner concludes that claims 1-3 and 5 are *prima facie* obvious over the combination of the two references.

The Examiner has not made out a *prima facie* case of obviousness. An important aspect of the claimed invention is the formation of an unstable solution on the surface of a slide by applying at least two stable solutions independently to the slide and thereafter mixing the stable solutions, on the slide and in the presence in the biological materials undergoing testing to form an unstable staining solution.

Neither McCormick et al. or Copeland et al. expressly disclose either the application of unstable staining solutions onto a biological material or the sequential application of stable solutions to a biological material to form an unstable solution. Since the McCormick et al. and Copeland et al. references are completely silent about the stability of the solutions that are applied to biological materials, there can be no *prima facie* case of obviousness since important elements of the claimed inventions are not found in the prior art of record.

It appears in this case that the Examiner is improperly analyzing the prior art in hindsight with the Applicant's invention in mind. The Examiner appears to be making the assumption that the McCormick et al. and/or Copeland et al. methods and devices use stable solutions to form an unstable staining solutions in view of Applicants' teaching in the present application that such unstable solutions are commonly used for staining biological materials. However, there is absolutely no teaching in McCormick et al. or Copeland et al. about the stability of the reagents used in the method described in either patent. Since there is no express teaching in the prior art of record about the stability of the reagents used in the patented methods and devices, there can be no *prima facie* case of obviousness.

B. The McCormick et al., Copeland et al, and McManus et al. Rejection

Claims 1-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al., in view of Copeland et al. and further in view of the McManus et al. article. The

Examiner's grounds for rejecting claims 1-9 under the references identified above is essentially the same as summarized in Section A above except that the Examiner has cited McManus et al. for disclosing standard staining solutions including staining solutions that are mixed just prior to use from stable stock solutions to form staining solutions that are unstable for storage.

Claims 1-9 are patentable over the prior art of record for the same reasons set forth in Section III, A above. The McCormick et al. and Copeland et al. references do not identify whether or not the solutions that are applied to biological materials are stable or unstable. For this reason, every element of the claimed invention is not found in the prior art of record and the Examiner's obviousness rejection should be withdrawn.

Conclusion

For the reasons indicated above, claims 1 –2 and 4-12 are believed to be patentable over the prior art of record. Favorable reconsideration and allowance of the pending application is, therefore, courteously solicited.

Respectfully submitted,

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Appendix A
Marked Up Claims Pursuant To 37 CFR 1.121

1. (Once amended) An automated method for staining biological materials on a slide, comprising:

a) providing at least a first and second stable solution, wherein the at least first and second stable solutions [when combined comprise]form an unstable staining solution when combined;

b) providing a slide, wherein a biological material to be stained is present on the slide;

[c) providing an automated delivery system to deliver a predetermined quantity of the at least first and second stable solutions to the biological material on the slide;] and

[d]c) sequentially applying the at least first and second stable solutions to the biological material on the slide using [the]an automated delivery system.

6. (Once amended) An automated method for silver staining biological materials on a slide, comprising:

a) providing a first stable solution of from about 0.2% to about 1.0% silver nitrate[, wherein the silver nitrate is at least first and second stable solutions when combined comprise an unstable staining solution];

b) providing a solution of from about 2.0% to about 4.0% methenamine;

c) providing a solution of from about 0.2% to about 0.6% borax;

d) providing a slide, wherein a biological material to be stained is present on the horizontal slide;

e) providing an automated delivery system to deliver a predetermined quantity of the silver nitrate, methenamine, and borax solutions to the biological material on the slide;

f) sequentially applying the silver nitrate, methenamine, and borax solutions to the biological material on the slide using the automated delivery system; and

g) mixing the silver nitrate, methenamine, and borax solutions to form an unstable staining solution associated with [stain] the biological material.